

**VIII. Summary of Safety and Effectiveness**

**SUBMITTER:** VERTEBRON Inc.  
400 Long Beach Blvd.  
Stratford, CT 06615  
(203) 380-9340

**CONTACT PERSON:** Luis Nesprido  
Regulatory Affairs, Manager

**DATE PREPARED:** September 2005

**CLASSIFICATION NAME:** Spinal Intervertebral Body Fixation Orthosis (888.3060)

**COMMON NAME:** Cervical Plating System

**PROPRIETARY NAME:** VERTEBRON SCP™ Cervical Plate System

**PREDICATE DEVICES:** VERTEBRON SCP™ Cervical Plate System – K040003 and K043181

**DEVICE DESCRIPTION:** The Reduced Stature VERTEBRON SCP™ Cervical Plate System is comprised of non-sterile, single-use, titanium alloy components. The VERTEBRON SCP™ Cervical Plate System attaches to the vertebral body by means of self tapping and self drilling cervical screws. This system's design is intended to stabilize the spinal operative site during the fusion process of a bone graft in the disc space. This submission adds a reduced stature cervical plate.

**INTENDED USE:** The VERTEBRON SCP™ Cervical Plate System is intended for non pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients. The VERTEBRON SCP™ Cervical Plate System is intended for non cervical pedicle fixation for the following indications: spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

**MATERIALS:** The material used is titanium Alloy material that conforms to ASTM F136.

**Substantial Equivalence:** Testing in accordance with ASTM F1717 was performed and demonstrated that the Reduced Stature VERTEBRON SCP™ Cervical Plate System is substantially equivalent to the DOC Cervical Stabilization System (K982443), ORION Anterior Cervical Plate (K973854), Synthes CSLP (K971883, K000536), ABC

K051815

Cervical Plate (K974706), EBI VueLock Anterior Cervical Plate (K010003, K023133) and VERTEBRON SCP™ Cervical Plate System (K040003 and K043181) which have received market clearance by the FDA.

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OCT 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Luis Nesprido  
Regulatory Affairs Manager  
Vertebron, Inc.  
400 Long Beach Boulevard  
Stratford, Connecticut 06615

Re: K051815

Trade/Device Name: VERTEBRON SCP™ Cervical Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: II  
Product Code: KWQ  
Dated: September 15, 2005  
Received: September 22, 2005

Dear Mr. Nesprido:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2- Luis Nesprido

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over the typed name.

Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**V. Indications for Use**

510(k) Number (if known): K051815

Device Name: VERTEBRON SCP™ Cervical Plate System

Indications For Use:

The VERTEBRON SCP™ Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions. The SCP™ Cervical Plate System can be implanted in the sub-axial cervical spine from C3 through C7 levels.

Prescription Use:   X    
(Per 21 CFR 801 Subpart D)

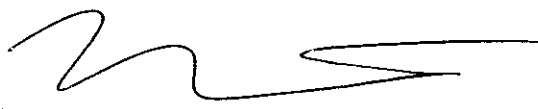
AND / OR

Over-The-Counter Use: \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

**510(k) Number** K051815

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